UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al., ex rel.* ADAM HART,

Plaintiff,

v.

MCKESSON CORPORATION, *et al.*,

Defendants.

15-CV-0903 (RA)

OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

Plaintiff-Relator Adam Hart brought this *qui tam* action against McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (collectively "McKesson") on behalf of the United States of America and twenty-eight states. In the main, Hart alleges that McKesson offered "something of value" to oncology practices that joined programs requiring them to purchase a substantial proportion of their drugs from McKesson—namely, two business-management tools, the Margin Analyzer and the Regimen Profiler, which allowed the practices to increase their profit margins for prescribed medications—and that doing so violated the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq*. ("AKS"). Claims for reimbursement submitted by these practices, Hart asserts, were tainted by the kickback scheme and thus in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"), and its state analogues.

The Court previously dismissed the First Amended Complaint filed in this action, finding that, although Hart had plausibly alleged that the business-management tools at issue constituted remuneration under the AKS, he failed to plausibly allege that McKesson acted with the requisite

scienter and failed to plead the fraudulent scheme with particularity as required by Federal Rule of Civil Procedure 9(b). *See United States ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575 (S.D.N.Y. 2022) (the "Prior Opinion"). The Court granted leave to amend, and Hart has since filed a Second Amended Complaint (the "Complaint"), adding new allegations which, he claims, plausibly allege that McKesson had knowledge of the unlawfulness of the scheme. McKesson has again moved to dismiss. For the reasons that follow, the motion is granted, albeit again without prejudice.[1]

BACKGROUND

The facts giving rise to this action, most of which were also detailed in the Court's Prior Opinion, are by now familiar to counsel and the parties. New allegations, as relevant here, are described in Section VI, *see infra* at 11–12. All facts are taken from the Complaint and are assumed to be true for purposes of the present motion. *See Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).

I. The Parties

McKesson Corporation is a Delaware corporation headquartered in Irving, Texas. Compl. ¶¶ 16, 17. McKesson sells pharmaceuticals, medical supplies, and related services to health care providers. *Id.* ¶¶ 2, 42. McKesson Corporation is the parent company of the other McKesson Defendants, "which are all wholly-owned direct or indirect subsidiaries of McKesson Corporation." *Id.* ¶ 16. McKesson Specialty Distribution LLC is a Delaware limited liability company and a wholly owned subsidiary of McKesson Corporation. *Id.* ¶ 17. McKesson Specialty

[1] As described *infra* at 16, 28, the Court concludes that amendment to salvage the claims brought under the False Claims Act analogues of the twenty-eight states and the District of Columbia would not necessarily be futile. Accordingly, it determines that dismissal without prejudice is once again warranted, although skeptical that federal jurisdiction would be proper with further amendment to exclusively bring those state law claims. *See* 28 U.S.C. § 1367(c)(3).

Care Distribution Corporation is a Delaware corporation and also a wholly owned subsidiary of McKesson Corporation. *Id.*[2] Hart alleges, upon information and belief, that during the relevant time period, McKesson Specialty Health ("MSH") was a business unit of McKesson Corporation, McKesson Specialty Care Distribution Corporation, and McKesson Specialty Distribution LLC. *Id.* Through MSH, McKesson operated as a wholesale distributor, buying specialty drugs and reselling them to customers across the country. *Id.* ¶¶ 2, 17–18, 42.

Plaintiff-Relator Hart was employed by McKesson from August 2011 until September 2014 as a Business Development Executive ("BDE") in its Specialty Health business unit. *Id.* ¶ 15. His responsibilities included generating new business opportunities among community-based oncology practices in the southeastern United States. *Id.* Once a customer was recruited, Hart would provide services for the first year, after which a "McKesson Account Executive" was assigned. *Id.* The McKesson Account Executive was responsible for maintaining and increasing sales, but Hart remained in touch with practices through "sales meetings, sales calls, requests for assistance from other personnel, and communications with coworkers." *Id.*

II. McKesson's Oncology Business

As relevant here, MSH provided "specialty pharmaceuticals and services to community oncology practices." *Id.* ¶ 49.[3] The specialty drugs used in cancer treatment are complex to manufacture, require special handling, and, as a result, are more expensive than other drugs. *Id.* ¶ 41. Some oncology practices obtain the drugs from a specialty pharmacy, which then bills patients' insurers. *Id.* ¶ 43. Others opt to purchase drugs from wholesalers like McKesson, provide

[2] In or around May 2013, McKesson Specialty Care Distribution JV LLC merged with McKesson Specialty Care Distribution Corporation, which became the surviving company. Compl. ¶ 17.

[3] Community oncology practices provide oncology care in an "office setting," as opposed to providers who operate in a hospital setting. Compl. ¶ 43.

those drugs to their patients, and then bill the patients' insurers themselves. *Id.*

In 2014, the oncology business was MSH's largest line of business by revenue, generating $7 billion of MSH's $9 billion in annual revenue. *Id.* ¶ 49. There were two divisions of the oncology business, and Hart worked in the "open market" division, which operated as a traditional drug wholesaler and distributor. *Id.* ¶¶ 49–50. The allegations in the complaint are limited to the practices of the open market division. *Id.* ¶¶ 50–51.

III. The Business-Management Tools

Hart's claims are based on McKesson's usage of two business-management tools—the Margin Analyzer and the Regimen Profiler—which were offered almost exclusively to practices that committed to purchasing a significant portion of their drugs from McKesson. *Id.* ¶ 75.

A. The Margin Analyzer

Beginning in approximately 2011, McKesson offered its customers "complimentary access" to the Margin Analyzer. *Id.* ¶ 54. With the benefit of further amendment, the Complaint now specifies a "non-exhaustive" list of 113 practices from locations throughout the country which were provided the Margin Analyzer free of charge. *Id.* ¶ 55. Among other things, the tool allowed oncology practices like these to compare the reimbursement rates of interchangeable drugs. *Id.* ¶¶ 58–59. McKesson had identified "therapeutically interchangeable" choices for ten categories of drugs commonly used by oncology practices. *Id.* ¶ 64. For any given category, the Margin Analyzer relied on pricing and reimbursement data to determine which of the similar drugs would yield the highest profit for the practice. *Id.* ¶¶ 65, 67. McKesson employees input reimbursement data from Medicare and private insurers, allowing the tool to analyze the profitability of different drugs based on a patient's insurer. *Id.* ¶¶ 61–63, 65–67.

By way of illustration, the Complaint includes the following illustration of the tool's utility. The Margin Analyzer listed five "therapeutically interchangeable" options for parenteral irons.

Id. ¶ 86. In Q1 2012, McKesson's data showed that, for Medicare-insured patients, the difference between acquisition cost and reimbursement price was significantly greater for one brand of parenteral irons, Feraheme, than other brands. *Id.* ¶¶ 86–87. For Summit Cancer Care in Savannah, Georgia, specifically, a switch from prescribing only Infed parenteral irons (margin of $15.19 per dose), to a mix of 80% Feraheme (margin of $88.52 per dose) and 20% Infed would increase annualized net profits by $10,560. *Id.* The Margin Analyzer excerpt below shows the type of data comparisons available to McKesson representatives and the practices with whom they shared them:

					COST / DOSE			MEDICARE				
Drug	Dose (mg's)	Dose Cost	Dose ASP+6%	Dose AWP	Drug	Admin	Cost/cycle Total	Drug	Admin	MDCR Allowable Total	Net Profit $	Net Profit %
INFED 50MG/	1000	$ 246.75	$ 241.94	$ 377.00	$ 246.75	$ 100	$ 347	$ 241.94	$ 120	$ 362	$ 15.2	4%
DEXFERRUM	1000	$ 235.62	$ 241.94	$ 377.00	$ 235.62	$ -	$ 236	$ 241.94	$ -	$ 242	$ 6.3	3%
NULECIT 12.5	1000	$ 351.89	$ 309.28	$ 610.56	$ 351.89	$ -	$ 352	$ 309.28	$ -	$ 309	$ (42.6)	-14%
FERAHEME 3	1020	$ 559.18	$ 647.70	$ 948.60	$ 559.18	$ -	$ 559	$ 647.70	$ -	$ 648	$ 88.5	14%
VENOFER 20	1000	$ 320.00	$ 290.00	$ 430.00	$ 320.00	$ -	$ 320	$ 290.00	$ -	$ 290	$ (30.0)	-10%

Compl., Ex. 4 at 7 (Q2 2012 SCC Margin Analyzer).

The Margin Analyzer was used not only to compare the cost and profit margin on a per drug, per insurer basis, but also to give forward-looking recommendations based on that data. BDEs or Account Executives were thus able to forecast various scenarios by inputting different drug mixes or potential payors, and then used those findings to aid the practices in choosing a drug distribution that was most profitable for the practice. *See* Compl. ¶¶ 82–87. Because the Margin Analyzer allowed practices to instantly compare the profit margin of one drug versus others in the same category, a BDE or Account Executive could identify areas with large profit opportunities. *See id.* McKesson personnel met with their customers at "Quarterly Business Reviews" to review the Margin Analyzer and to provide "a detailed analysis of the practice's finances and business operation." *Id.* ¶ 71.

In order to generate these results, the Margin Analyzer required data, including: the fee schedules published quarterly by the Centers for Medicare and Medicaid Services ("CMS"); the customer's quarterly purchase records; the prices at which McKesson sold its drugs; and the fee schedules of relevant private insurers. *Id.* ¶¶ 60–62. McKesson employees would gather and input this data into spreadsheets for each practice, and update them on a quarterly basis as the data changed. *Id.*

Because different insurers reimbursed different drugs at different rates, a drug most profitable for a Medicare patient may not be as profitable for a patient with a given private insurer. The Margin Analyzer not only accounted for the different reimbursement amounts offered by different insurers, but synthesized the data into a "cheat sheet" page that recommended the most profitable drug in each category by payor. *See id.* ¶¶ 90–91; *id.*, Ex. 3, Q4 2012 SCC Margin Analyzer. The "cheat sheet" generated for the Summit Cancer Care in Q4 of 2012, for example, recommended one of three different antiemetic drugs, *see* Compl. at ¶ 91, depending on whether the patient was covered by BlueCross BlueShield, Cigna, or Medicare, as seen below:

		BCBS PAR	Cigna	Aetna	Medicare	Humana	UHC	Coventry GA
AntiEmetics	ALOXI		X					
	GRANISETRON	X				X		
	ONDANSETRON			X	X		X	X

Id., Ex. 3 at 3 (Q4 2012 SCC Margin Analyzer). As with all of the data in the Margin Analyzer, McKesson would update these sheets every quarter as reimbursement rates changed. Compl. ¶¶ 93–94. The most cost-effective drugs were subject to change each quarter. *Compare id.*, Ex. 3, Q4 2012 SCC Margin Analyzer, *with id.*, Ex. 5, Q1 2013 SCC Margin Analyzer.

McKesson used the Margin Analyzer in three contexts: to acquire new customers and/or retain existing customers, *id.* ¶ 70; to provide consultation and financial advice to existing

customers at in-person "Quarterly Business Reviews," *id.* ¶ 71; and to encourage the purchase of new drugs (or drugs with new pricing), *id*. ¶ 72.

B. The Regimen Profiler

The Regimen Profiler worked in much the same way as the Margin Analyzer, but rather than calculate the margins for an individual drug, it calculated costs for the whole treatment regimen. *Id*. ¶¶ 6, 106. Oncology practices typically incur significant non-drug related costs in the administration of cancer therapy, including the cost of preparing or administering the treatments, such that the price of the drug itself is only one component of the overall cost. *Id.* ¶¶ 107, 109. The Regimen Profiler filled this gap—calculating profit margins for the course of treatment, including non-drug costs. *Id*. Insurers reimbursed these non-drug costs as well, and so the Regimen Profiler, like the Margin Analyzer, calculated the profitability of each treatment regimen on a provider-by-provider basis. *Id*. ¶ 109. The tool was designed to be used in conjunction with the Margin Analyzer to understand a practice's overall profitability and/or potential profitability. *See id.*, Ex. 1 (Margin Analyzer Sales Sheet). McKesson employed the Regimen Profiler in the same manner as the Margin Analyzer—to pitch new customers and retain existing ones. Compl. ¶ 112. Moreover, as with the Margin Analyzer, McKesson made an "explicit contractual promise" only to commitment program customers to provide the Regimen Profiler free of charge. *Id.*

C. McKesson's Offer of the Business Management Tools to Commitment Program Customers

Hart alleges that these tools were provided, for free, on a quarterly basis, to a number of oncology practices throughout the country. They were not, however, distributed to all of McKesson's customers. Instead, the Margin Analyzer and Regimen Profiler were offered, "with few (or no) exceptions. . . *only* to physician practices that contracted to join the Onmark Select,

Prime, or MVP programs." *Id.* ¶ 75 (emphasis in original). The Onmark Select, Prime Membership, and McKesson Value Program ("MVP") (collectively the "commitment programs"), required practices to purchase a certain volume of their drugs from McKesson. *Id.* ¶ 74. The Onmark Select program required use of McKesson as the "primary wholesale supplier" for branded and generic drugs, while the Prime and MVP programs required a commitment to purchase approximately 90% to 95% of the practice's branded and generic drugs from McKesson. *Id.*

If they did not join one of the commitment programs, oncology practices were still able to purchase drugs from McKesson. But MSH did not allow non-commitment program customers to access the business-management tools. *Id.* ¶¶ 76, 112. One practice, for instance—Hematology Oncology of the Treasure Coast—sought to end its purchase commitment with McKesson, and was explicitly told that, if it did so, it would lose access to the Margin Analyzer. *Id.* ¶ 76.

Although his First Amended Complaint named twelve practices that were allegedly offered these tools for free and signed commitment programs with McKesson, Hart's Second Amended Complaint now alleges a far larger number of practices which fit into this category—including such diverse practices as Commonwealth Hematology Oncology in Quincy, Massachusetts; Rocky Mounty Oncology Center PLLC in Casper, Wyoming; Katmai Oncology Group in Anchorage, Alaska; and Oncare Hawaii, Inc. in Honolulu, Hawaii. *Id.* ¶ 55. In all, Hart's Complaint now lists 113 practices from across some thirty states and the District of Columbia, *see id.*, which were allegedly "offered the Margin Analyzer and/or the Regimen Profiler for free as an inducement to make a purchase commitment from McKesson." *Id.* ¶ 79. The Complaint further claims that

> During the sales pitch to practices like those identified in Paragraph 55, McKesson would populate the Margin Analyzer with the practices' specific drug utilization information to demonstrate the utility of the Margin Analyzer. The physician practices then signed purchase commitments with McKesson and informed

> McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their decision to commit to buying specialty drugs from McKesson.

Id. ¶ 80. Hart further alleges that, in addition to the practices named in the Complaint, this conduct occurred nationwide. *Id.* ¶ 134.

Hart's complaint also contains allegations that suggest McKesson knew that the Margin Analyzer and Regimen Profiler were valued by its customers. Sales training materials attached to the complaint emphasized the importance of the Margin Analyzer to retaining customers. And McKesson purportedly believed that the tools were important to both enhancing its profitability and creating "stickiness" among its customers. *Id.* ¶ 78; *id.* Ex. 9 at 8–9 (2014 South Region Meeting Presentation) (describing the importance of "creat[ing] stickiness" through "value-added services"). Hart also references internal communications in which McKesson concluded at least some customers stayed with McKesson, over lower cost providers, in order to retain access to the Margin Analyzer. *Id.* ¶ 70 ("McKesson acknowledged in internal communications that it has practice group customers who refuse to leave MSH for lower cost providers of specialty drugs because those practices would lose access to the Margin Analyzer in the event they did so."). The company even allegedly prepared a "customer testimonial video" dedicated to the business-management tools, touting their potential value to community oncology practices. *Id.* ¶ 130.

McKesson's view that the tools were important to customer acquisition and retention was purportedly further emphasized at its in-person sales conferences. At those events, executives from McKesson made clear that the Margin Analyzer and Regimen Profiler should be at the center of sales pitches to new customers. *Id.* ¶¶ 76, 123–26, 146. Indeed, according to Hart, the Margin Analyzer and Regimen Profiler were "so central to McKesson's business that McKesson fired one BDE because he was not sufficiently emphasizing the Margin Analyzer and the Regimen Profiler

in his sales pitches." *Id.* ¶ 125.

IV. The Anti-Kickback Statute and False Claims Act

The AKS and FCA work in conjunction to create a private right of action for violation of the federal criminal anti-kickback statute. The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)–(B). Claims are defined as "any request or demand for money from an officer, agent, employee, or contractor of the United States." 31 U.S.C. § 3729(b)(2)(A).

The AKS prohibits any individual or entity from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or arrange for or recommend purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §1320a-7b(b)(2)(B). Claims resulting from an AKS violation constitute "a false or fraudulent claim" for the purposes of the FCA. 42 U.S.C. §1320a-7b(g); *see also United States v. Novartis Pharms. Corp.*, 2020 WL 1436706, at *1 (S.D.N.Y. Mar. 24, 2020).

V. Procedural History

Plaintiff filed his initial complaint on February 6, 2015. Because the action was brought under the False Claims Act, the complaint was placed under seal to afford the government an opportunity to intervene. *See* 31 U.S.C. § 3730(b)(2). The government ultimately declined to intervene, and the complaint was unsealed as of May 29, 2020. Plaintiff then filed the First Amended Complaint, which stated claims against McKesson under the FCA, as well as under the False Claims Act analogues of twenty-eight states and the District of Columbia, based on the same alleged conduct.

On May 5, 2022, the Court granted McKesson's motion to dismiss the First Amended Complaint, finding that although the First Amended Complaint plausibly alleged that the Margin Analyzer and Regimen Profiler constituted "remuneration" under the AKS, and that they "have substantial value apart from the products offered by McKesson," Prior Opinion, 602 F. Supp. 3d at 586–87, Hart had not adequately pleaded McKesson acted with the scienter required under the AKS, *id*. at 592. *See also id*. at 594 (noting that the AKS requires allegations which "give rise to a plausible inference that McKesson knew its conduct was unlawful"). The Court reserved judgment on whether Hart had pleaded a nationwide scheme. *See id*. at 598.

Hart was granted leave to amend to correct the pleading issues identified in the Court's dismissal order. *See id.* at 598–99. He filed a Second Amended Complaint on June 7, 2022, *see* Dkt. 159, and McKesson once again moved to dismiss. the Court heard oral argument on the motion on March 15, 2023.

VI. The Second Amended Complaint's New Allegations of Scienter

Following the Court's prior dismissal—in addition to naming additional practices which were given the Margin Analyzer and Regimen Profiler free of charge, and further allegations regarding McKesson employees' general awareness of the AKS—Hart added two new sections to the Complaint. The first, entitled "Additional Allegations of Scienter," includes allegations about previously undescribed conversations between Hart and other McKesson employees about the possibility that the company's provision of the tools may violate the AKS. Compl. ¶¶ 163–66. In key part, this section alleges that an Ernst & Young analysis valuing the Margin Analyzer and Regimen Profiler at $125,000 and $25,000 per year, respectively, was sent to several McKesson executives. *Id*. ¶ 160. According to Hart, McKesson's Senior Vice President of Open Market Sales then emailed a presentation containing those valuations to the Vice President of Payer and Revenue Cycle Services, with a note in the body of the email stating: "You didn't get this from

me . . . ok?" *Id.* (ellipses in original). The section further alleges that, while at a live web-based training on the AKS, Hart sent an instant message to his supervisor "stating that McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session," and that his concerns were "dismissed." *Id.* ¶ 164. Finally, the section alleges that Hart had "frequent conversations" with the creator of the Margin Analyzer while the two were traveling for sales pitches, and that they discussed concerns that McKesson was "inappropriately exploiting the value-added business tool." *Id.* ¶ 166.

The second additional section, "McKesson Has Destroyed Documents Evidencing Its Conduct," boldly alleges that McKesson purposefully destroyed evidence relevant to the present action. *Id.* § VII(G). It asserts that "McKesson has shown knowledge of guilt" by "taking steps to conceal evidence of its prior activity." *Id.* ¶ 167. "For example, although [McKesson] previously touted the Margin Analyzer on its website, including through a customer testimonial video," the Complaint alleges, it "has since taken down the video and claimed to have lost or destroyed [it]." *Id.* So too, the section details the "destr[uction] [of] critical documents relating to the allegations in this case, even after it had a duty to preserve such documents." *Id.* ¶ 168.

LEGAL STANDARD

When considering a motion to dismiss under 12(b)(6), a court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." *LaFaro v. New York Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009) (cleaned up). The complaint must "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face,'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)), and must be dismissed if it fails to state a claim upon which relief can be granted,

see Fed R. Civ. P. 12(b)(6). A complaint that offers only "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action, will not do.'" *Id.* (quoting *Twombly*, 550 U.S. at 555). Nor will a complaint suffice if it contains only "'naked assertion[s]' devoid of further 'factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Because FCA claims "fall within the express scope of Rule 9(b)," *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam), a relator must "state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b). While the circumstances of the fraud must be pled with particularity, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" under Rule 9(b). Fed. R. Civ. P. 9(b). Where an FCA claim is predicated on a violation of the AKS, both the FCA and AKS violations must be pled in compliance with Rule 9(b). *United States v. Novartis Pharms. Corp.*, 2020 WL 1436706, at *3 (S.D.N.Y. Mar. 24, 2020) (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617-18 (2d Cir. 2016) and *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513-14 (S.D.N.Y. 2014)). Claims under the FCA state analogues must also satisfy Rule 9(b). *Novartis*, 2020 WL 1436706, at *3 (citing *United States ex. rel. Arnstein v. Teva Pharms. USA, Inc.*, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) ("*Arnstein*")). To satisfy Rule 9(b)'s heightened pleading requirement, a complaint must "adduce specific facts supporting a strong inference of fraud." *United States ex rel. Chorches for Bakr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 82 (2d Cir. 2017).

DISCUSSION

In its motion to dismiss, McKesson contends that the Second Amended Complaint remains unable to state a claim as a matter of law, as it still: (1) fails to plausibly allege that Defendants acted with the required scienter under the AKS; and (2) fails to plead the fraudulent scheme with

particularity. For the reasons that follow, the Court finds that, even with the benefit of specific instruction on the failings of the First Amended Complaint in the Court's Prior Opinion, a year of discovery, and another chance to amend his pleadings, Hart has failed to include sufficient factual allegations to support a plausible interference that McKesson acted with knowledge that its conduct was unlawful, as required under the federal AKS.[4] The Court therefore grants McKesson's motion, and dismisses the Second Amended Complaint.

I. Hart Fails to Plausibly Allege that McKesson Acted with the Requisite Scienter

The AKS prohibits a person from "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Hart is not only required to plead that McKesson offered these tools to its customers, but that it did so with a culpable—*i.e.*, "knowing[] and willful[]," *id.*—mental state.

A. The Scienter Requirement of the AKS

Where an FCA claim is based on a violation of the AKS, the AKS scienter requirement must also be satisfied. As this Court previously held, "to satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful." Prior Opinion, 602 F. Supp. 3d at 595; *see also id.* at 593–94 (collecting cases and considering the legislative history). In the time since that opinion, the Second Circuit has confirmed this reading of the AKS. *See Pfizer, Inc. v. United States Dept. of Health and Human Servs.*, 42 F.4th 67, 77 (2d Cir. 2022). In *Pfizer*, the Circuit explained that, while a plaintiff need

[4] Because the Court finds that the requisite scienter was not alleged to state a claim under the AKS, it need not consider McKesson's arguments in the alternative that Hart has failed to plead the alleged fraud with sufficient specificity under Federal Rule of Civil Procedure 9(b).

not establish a defendant acted with a "bad purpose" or "corrupt intent" to state a claim under the AKS, the statute's use of "willful" means that it requires "a voluntary, intentional violation of a known legal duty"—for the defendant to "know[] that [its] conduct is illegal." *Id.* (quoting *United States v. Bishop*, 412 U.S. 346, 360 (1973)); *see also id.* (observing that "Congress added the willfulness element to the AKS to avoid punishing 'an individual whose conduct, while improper, was inadvertent'") (quoting H.R. Rep. 96-1167, at 59 (1980)). Put differently, because the "AKS does not apply to those who are unaware that [(conduct constituting kickbacks)] [is] prohibited by law and accidentally violate the statute," the statute requires proof of an "intentional violation of a known legal duty." *Id.*

Perhaps in light of the Circuit's statutory interpretation in *Pfizer*, Hart has declined to once again press his challenge as to the required mental state under the AKS, and now acknowledges that his Complaint must plausibly allege that McKesson acted with knowledge that its conduct was illegal. Opp. at 5. Nevertheless, Hart continues to argue that such knowledge can be shown via a two-step set of allegations. Specifically, he asserts that, where pleadings allege that a defendant "(1) knows that the AKS prohibits the provision of anything of value as an inducement, yet (2) engages in intentional conduct to provide things of value as inducements anyway," such allegations state a claim under the AKS. Opp. at 5.

Such a two-step approach, however, was specifically rejected by this Court before. *See* Prior Opinion, 602 F. Supp. 3d at 595–96 (observing that "awareness of the requirements of the AKS and the general unlawfulness of inducements" coupled with "facts to support the conclusion that the tools may constitute 'remuneration'" were not enough to "support a finding that McKesson knew this particular course of conduct was unlawful"). The same argument from Hart now merits the same conclusion. Hart's Complaint must contain factual allegations from which the Court can

plausibly infer that McKesson acted with the knowledge that its conduct—offering the Margin Analyzer and Regimen Profiler free of charge to oncology practices that contracted to join the programs requiring them to purchase a certain volume of McKesson drugs—was unlawful. *See United States ex rel. Suarez v. AbbVie Inc.*, 2019 WL 4749967, at *13–*14 (N.D. Ill. Sept. 30, 2019) ("*Suarez I*"); *see also United States ex rel. Forney v. Medtronic, Inc.*, 2017 WL 2653568, at *4–5 (E.D. Pa. June 19, 2017).

Hart's argument in the alternative that the Complaint's state law claims should survive, even failing plausible allegations of scienter under the federal AKS, also fails. To be sure, Hart does bring claims under the False Claims Act analogues of twenty-eight states and the District of Columbia. *See* Compl. ¶ 13 (citing each of the state FCAs, such as the California False Claims Act, Cal. Gov't Code § 12650 *et seq*.). And, as Hart argues, some of those state law regimes have anti-kickback statutes of their own which do not incorporate a "willfulness" scienter requirement as does the federal AKS. *See* Opp. at 4 n.1 (citing Tex. Hum. Res. Code §§ 36.0011(a), 36.002(12)). But Hart's complaint here does not allege a violation of the states' FCA analogues by way of kickbacks under each of those state law regimes. Rather, it alleges that "Defendants' actions . . . also violate the laws of the States, each of which has enacted a false claims act analogous to the federal FCA, each of which requires compliance *with* ***the AKS*** as a condition of payment of Medicaid reimbursement . . . ." Compl. ¶ 13 (emphasis added). Put differently: his Complaint brings claims under both the federal FCA and the states' FCAs by way of a violation of the *federal AKS*.

Accordingly, as in its Prior Opinion, the Court treats the state law claims together with the federal claims, as each here ultimately require—but are missing—plausible allegations of the requisite scienter under the federal AKS.

B. Hart's Amended Allegations of Scienter

Hart's Complaint now includes allegations of conversations he shared with other McKesson employees about the purportedly "inappropriate" nature of the company's use of the business tools in sales, allegations related to an email containing valuations of the tools shared by a company executive, and additional allegations regarding McKesson's general trainings on the AKS. For the reasons that follow, none of these allegations suffice to plausibly allege that McKesson acted with knowledge that providing the Margin Analyzer and Regimen Profiler free of charge to certain oncology practices was unlawful.

First, Hart now claims that he sent an instant message to his direct supervisor, Bennett Holtzman, during a live web-training presentation on McKesson's compliance policies that they were both attending. Hart alleges that the message stated:

> that McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session. Holtzman dismissed [Hart's] concerns and responded by instructing [him] to continue his sales work and not to worry about the compliance policies that prohibited the sales practices that [Hart] . . . had been instructed by McKesson executives to use.

Compl. ¶ 164. This message and response, however, falls short of alleging that McKesson knew that its conduct was unlawful. As the court in *United States ex rel. Fitzer v. Allergan, Inc.* ("*Fitzer I*"), held, "the fact that Relator told Allergan that *he* believed the physician locator violated the AKS . . .[does not] indicate[] that *Allergan* was acting with malintent." 2021 WL 4133713, at *7 (D. Md. Sept. 10, 2021) (emphasis added); *see also United States ex rel. Fitzer v. Allergan, Inc.*, 2021 WL 5840874, at *4 (D. Md. Dec. 9, 2021) ("*Fitzer II*") (noting the allegation "that Relator told Allergan it was violating the AKS provides no facts that relate to Allergan's state of mind"). If anything, the allegations here are even weaker than those at issue in *Fitzer I*. There, the relator specifically indicated that the conduct at issue, Allergan's provision of a "physical locator,"

violated the AKS. Here, by comparison, the Complaint only goes so far as alleging that Hart indicated that McKesson's general "sales practices" (which, through artful pleading, he alleges "included using the Margin Analyzer and Regimen Profiler") violated the company's compliance policies. Compl. ¶ 164.

Hart's attempt, moreover, to liken his allegations of these instant messages to the later-filed amended complaint in *Fitzer II*, which ultimately survived a motion to dismiss, is unavailing. The *Fitzer II* court specifically noted that it was the third amended complaint's allegation that the vice president of sales "debate[d]" the legality of the scheme, and said that he would raise it with the CEO, which finally sufficed to allege the requisite scienter. *Fitzer II*, 2021 WL 5840874, at *3–4. At most, Hart here alleges that he raised generalized compliance concerns to his immediate sales supervisor via instant messenger during a training. That conversation is unlike the final iteration of the pleadings in *Fitzer II*, wherein unlawful conduct was raised to the highest levels of the defendant company, and those complaints were considered and nevertheless disregarded. *See* 2021 WL 5840874, at *4. Instead, just like the dismissed second amended complaint in *Fitzer I*, *see* 2021 WL 4133713, at *7, a general statement made to a regional manager that "current sales practices" violated "compliance policies," Compl. ¶ 164, will not do to allege that McKesson was knowingly violating the law.

Similarly, Hart's allegations of newly recalled conversations with fellow McKesson sales employees about how the use of the Margin Analyzer and Regimen Profiler was "unethical" and "wrongful," *id*. ¶¶ 165–66, are insufficient to plausibly allege that the company had the requisite scienter. Specifically, Hart asserts that he shared his concerns about the tools given that they purportedly encouraged customers to purchase "the highest margin drugs," therefore leading to

higher costs for patients and payors. *Id*.[5] He also describes a conversation he shared with another employee about how it was "inappropriate" for McKesson to provide the Margin Analyzer to Open Market customers because it had been "created originally" for customers of U.S. Oncology (USON"). *Id*. ¶ 166. As in *Fitzer I*, allegations about things that *Hart* said to other sales employees within the company, without more, does not establish what *McKesson* believed about offering the business tools to oncology practices. *See Fitzer I*, 2021 WL 4133713, at *7. But even if the Court were to credit Hart's allegations as somehow speaking to the company's knowledge, beliefs about the "inappropriate" or "unethical" nature of providing the business tools is, without more, insufficient to adequately plead purported knowledge of *unlawfulness*—let alone an "intentional violation of a known legal duty," *Pfizer*, 42 F.4th at 77.

Second, Hart attempts to allege McKesson knew of the illegality of providing the Margin Analyzer and Regimen Profiler based on an email from Kirk Kaminsky, then the Senior Vice President of Open Market Sales, forwarding certain USON documents to Dianna Verrilli, Senior Vice President of Payer Solutions, with a cover message reading: "You didn't get this from me . . . ok?" Compl. ¶ 160. The Court is unpersuaded that the Complaint's reliance upon this email and its attachments plausibly alleges knowledge of unlawfulness.

As an initial matter, although the Complaint did not specifically attach the email or its attachments, the Court may consider these documents because they were incorporated by reference. *See In re Cocoa Servs., LLC*, 2018 WL 1801240 (Bankr. S.D.N.Y. Apr. 13, 2018) (quoting *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007) ("The materials that may be considered on a motion to dismiss are those 'asserted within the four corners of the

[5] The allegation that the tools would lead to practices necessarily prescribing the highest-cost drugs is inconsistent with other allegations in the Complaint. In the Complaint's attached Exhibit 3, for instance, the highest margin drug recommended to Summit Cancer Care was often a less-expensive option. *See, e.g.*, Compl., Ex. 3 (comparing ARANSESP, $1626.32 with a profit of -$454.04, with PROCRIP $1327.39 with a profit of $222.35).

complaint . . . and any documents incorporated in the complaint by reference.'")). Indeed, even if Hart had not incorporated the email and its attachments into the Complaint, given his extensive and specific reliance upon them to allege scienter, the Court "may nevertheless consider" them, as "the [C]omplaint relies heavily upon [their] terms and effect, which renders the document[s] 'integral' to the [C]omplaint." *Chambers v. Time Warner, Inc.*, 282 F.3d 147, 153 (2d Cir. 2002) (cleaned up).

With the benefit of the email and its attachments, it is not clear that the cover message relates to the Margin Analyzer or Regimen Profiler at all, or that information about the valuation of those programs, specifically, is what Kaminsky was referring to. The email attached three separate documents totaling 170 pages, each covering a range of materials—everything from physician compensation, *see* Pastan Decl., Ex. 1(b) at 8, to rates of return on invested capital, *see id*. at 14, to McKesson's vision insurance and retirement plans for employees, *see id*, Ex. 1(c) at 27–28. Indeed, the Margin Analyzer was only referenced three times, and the Regimen Profiler twice, across all of those pages—and even then, only in passing within descriptive cells of a 61-sheet table valuing a range of services, *see id.*, Ex. 1(b) at 27, 32, 37, and 53, or buried in the body of text on page 82 of an 84-page summary document, *see id*., Ex. 1(c) at 82.

In any event, even if the Court were to accept that Kaminsky's cover email *was* in reference to the tools, his message does not plausibly allege that he had any belief that McKesson's provision of the Margin Analyzer or Regimen Profiler free of charge was in any way unlawful. His message could have been included for any number of reasons: perhaps because Verrilli should not have been receiving materials from the Open Market business unit, for instance, or because Ernst & Young had only provided certain executives of the company with a draft assessment. These suppositions are not for the Court to make, as it is a plaintiff who must make the allegations

required to plausibly support his claims. In short: the documents attached do not lead to a plausible inference that the cover email was in reference to the business tools at issue—let alone that McKesson had knowledge of the purported illegality of offering them free of charge to select practices. *Contra* Compl. ¶ 160 (alleging the email "indicat[ed] [Kaminsky's] knowledge that McKesson's provision of these value-added business tools for free . . . was wrongful and unlawful").

Beyond the newly described conversations with fellow McKesson sales employees and the Kaminsky email, Hart's Complaint merely reiterates (albeit in more extended form) allegations that McKesson had general knowledge of the requirements of the AKS and the unlawfulness of inducements in violation of the statute. He alleges that internal company policies, for instance, prohibited providing of "things of value" to induce purchases of items that would ultimately be reimbursed by government sponsored health care providers, and that employees received trainings on the AKS's demands. *See, e.g.*, *id*. ¶¶ 143–45. But as the Court specifically observed in its Prior Opinion, allegations like these, even coupled with those that McKesson knew that the Margin Analyzer and Regimen Profiler were business tools with independent value, do not support an inference of scienter as required by the AKS. *See* 602 F.3d at 596 ("Allegations that McKesson knew remuneration to induce purchases was prohibited in general, however, cannot alone support a finding that McKesson knew this particular course of conduct was unlawful.").

The Complaint continues to lack specific allegations of the type that other courts have found to support a plausible inference of knowledge that the conduct was unlawful, such as actions taken to conceal the fraudulent scheme, *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); notice from counsel that the program may be unlawful, *United States v. Teva Pharms.*, 2021 WL 4132592, at

*6; *United States v. Millennium Radiology, Inc.*, 2014 WL 4908275, at *8 (S.D. Ohio Sept. 30, 2014); *United States ex rel. Banigan v. Organon USA Inc.*, 2016 WL 10704126, at *3 (D. Mass. Aug. 23, 2016) (internal document characterizing relationship as a "quid pro quo" was sufficient to establish dispute as to scienter at summary judgment stage); cancellation of the program due to concerns over its lawfulness, *United States ex rel. Wood v. Allergan, Inc*, 246 F. Supp. 3d 772, 829 (S.D.N.Y. 2017), *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018); or a service without legitimate value that was a pretext to provide remuneration, *Arnstein*, 2016 WL 750720, at *17 (describing relator's allegation that company-sponsored speaker programs were "shams").

To the contrary, the conduct complained of here was, based on the Complaint's own allegations and attached exhibits, openly advertised and even widely discussed. Such allegations undermine any claim that McKesson was intentionally violating a known legal duty. *See, e.g.*, *United States v. Novartis AG*, 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011) ("Plaintiffs do not allege any facts, circumstantial or otherwise, that Novartis believed, or acted in a way suggesting it believed, that its marketing . . . was illegal. Rather, and in contrast to other cases where the courts have found sufficiently pleaded AKS claims, Plaintiffs' amended complaint suggests Novartis allegedly paid kickbacks to physicians quite openly."). In *United States v. Valley Campus Pharmacy, Inc.*, for instance, the court observed that "Relator's allegations seem to indicate that Defendants thought their offering of PA services was lawful, as they advertised these services openly on their website and in a presentation in Las Vegas." 2021 WL 5406148, at *3 (C.D. Cal. Oct. 12, 2021), *aff'd* 2023 WL 195514 (9th Cir. Jan. 17, 2023). Allegations of open, public behavior "coincides more with merely the intent to use [the services at issue] as a 'sales and marketing tool,' and not a knowingly unlawful means of obtaining referrals." *Id.* As such, they "do not support a plausible inference of scienter" under the AKS. *Id.*

Hart's allegations that McKesson purportedly destroyed documents do not alter the Court's conclusion.[6] Taken as true for purposes of the present motion, these allegations do not give rise to the plausible inference that McKesson destroyed documents in order to conceal conduct it knew was unlawful. Rather, Hart alleges that McKesson removed references to the Margin Analyzer from it's public-facing website, *see* Compl. ¶ 167; that it no longer has the consumer testimonial video regarding those tools (which is nevertheless already described in substance by the Complaint), *see id*., and that it "does not appear to have maintained and/or preserved" records of either its employees' emails related to the business tools, or records of their AKS compliance training, *see id*. at 168–70. Apart from conclusory allegations that the ostensible destruction of these materials is evidence of "guilt" or that McKesson "knew its conduct was wrongful," however, the Complaint does not provide specific allegations to support the plausible inference that McKesson engaged in document destruction in order to conceal evidence which would demonstrate scienter under the AKS. *Contra, e.g., Burciaga v. GEO Grp., Inc.*, 2017 WL 10605270 (S.D. Cal. Feb. 28, 2017) (finding that the evidence that "Defendant destroy[ed] records to keep them from ACA auditors" was sufficient to meet the FCA scienter standard); *SEC v. Suterwalla*, 2008 WL 9371764 (S.D. Cal. Feb. 4, 2008) (alleging the plaintiff destroyed documents protected by an injunction in order to conceal fraud).

Moreover, the cases that Hart cites to argue that his new allegations plausibly allege

[6] While the Court does not rely on this for purposes of the present motion, and accepts each of the Complaint's allegations as true, it is worth noting that, during the course of discovery prior to the filing of the present Complaint, Magistrate Judge Cott considered at least some of Hart's accusations that McKesson had destroyed evidence—namely, those related to the destruction of materials on Hart's laptop, *see* Compl. ¶¶ 168, 170—and found them to be entirely unsupported. *See* Dkt. 138 (letter motion from Hart to Judge Cott raising the same allegations); Dkt. 144, Tr. (Jan. 12, 2022), at 5:17–20 ("I don't think there is enough in the record . . . to suggest that there was some improper destruction of these documents"); *id*. at 21:22–22:4 ("As presented [any document destruction] seems to have occurred in the normal course . . . companies like McKesson rightfully engage in appropriate destruction in the regular course."). It is true, however, as Plaintiff emphasized at oral argument before this Court, that Judge Cott did not consider specific allegations related to the destruction of a customer testimonial video, *see* Compl. ¶ 167, nor those related to the failure to preserve records of McKesson employees' AKS compliance training, *see id*. ¶ 169.

knowledge of illegality do not salvage his claims, as each are distinguishable. A first set of those cases included specific allegations that defendants were provided with (and reviewed) detailed information—at the highest levels of the business—about how the conduct complained of violated the AKS, and that such concerns were specifically considered. In *United States v. Teva Pharmaceuticals USA, Inc.*, 560 F. Supp. 3d 412 (D. Mass. 2021), for instance, the government highlighted the fact that Teva employees circulated a law firm's advice to the company "warning of the risks associated with donations to copay assistance charities" under the AKS, the specific conduct complained of in that action. *Id*. at 421–22. So too, in *United States v. Genesis Glob. Healthcare*, 2021 WL 4268279 (S.D. Ga. Sept. 20, 2021), the district court highlighted investment documents given to executives of the defendant company which "informed [them] about the AKS's prohibition against" the specific conduct complained of, and "warned that [the] investments . . . were suspect." *Id*. at *12. The *Genesis* court further described that, when defendant's executives specifically discussed the practice at an investor meeting, an "initial investor raised concerns about the scheme's legality under the AKS with [the executives] and subsequently backed out of the investment." *Id*. Allegations like these—evincing specific consideration regarding the legality of a given scheme under the AKS—suffice to allege that the defendant acted with knowledge that the scheme was unlawful. *See also, e.g., Strunck*, 2020 WL 362717, at *4 (citing allegations that company's VP received articles discussing the illegality of the at-issue conduct and knew similar conduct was unlawful). But the Complaint here—unlike in *Teva*, *Genesis*, or *Strunck*—contains no allegations that McKesson executives either received or considered advice regarding the legality of providing the Margin Analyzer and Regimen Profiler to select oncology practices.

Other cases relied upon by Hart involved distinct allegations that defendants were engaging

in conduct that either violated internal policies prohibiting the specific conduct as unlawful under the AKS, or which was widely recognized within the industry as illegal. In *United States v. Teva Pharmaceuticals USA, Inc.*, 2019 WL 1245656 (S.D.N.Y. Feb. 27, 2019), internal company guidance prohibited the specific conduct at issue in the action, based on the company's stated belief that such conduct may run afoul of the AKS. *See id*. at *9–12. Similarly, *United States ex rel. Bilotta v. Novartis Pharmaceuticals Co.* involved allegations that defendants had repeatedly violated internal policies and industry guidance related to speaker programs. *See* 50 F. Supp. 3d 497, 518–21 (S.D.N.Y. 2014). There, the pleadings alleged that Novartis ethics and compliance policies specifically required that speaker programs be held at venues "conducive to an exchange of medical information," and that food and beverages should be "ancillary to meaningful discussion" and "modest in quantity and cost." *Id*. at 519. The district court emphasized that "Novartis's conduct—as alleged in the pleadings—violates each of these policies, raising a strong inference that Novartis acted knowingly and willfully in using the speaker events to induce prescription-writing in violation of the anti-kickback laws." *Id*. Finally, *United States ex rel. Pasqua v. Kan-Di-Ki*, 2012 WL 12895229 (C.D. Cal. June 18, 2012), involved allegations that the conduct which was the subject of the action was "known throughout the health care industry" to violate the AKS "at the time Defendants engaged in such conduct." *Id*. at *5.

Here, by contrast, while Hart alleges that McKesson had general internal policies regarding the AKS, *see, e.g.*, Compl. ¶¶ 8, 157–59, he does not allege that it had specific policies warning that provision of the Margin Analyzer or Regimen Profiler to practices free of charge may have been unlawful. Similarly, Hart does not allege that providing business management tools like the Margin Analyzer and Regimen Profiler were widely recognized "throughout the health care industry" at the time, *Pasqua*, 2012 WL 12895229, at *5, to raise AKS-related concerns. Quite to

the contrary, the Complaint itself highlights that McKesson *openly advertised* the Margin Analyzer and Regimen Profiler tools, *see* Compl. ¶¶ 130, 167, and further attaches documents referencing similar business management tools provided by other healthcare companies at the time, *see* Dkt. 176-5 at 17 (McKesson analysis of competitor business tools). And, as the Court noted in the Prior Opinion dismissing the First Amended Complaint, at least some OIG guidance appears to have recognized that the provision of certain types of tools and support do not run afoul of the AKS. *See* 602 F. Supp. 3d at 589–90. The 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003), for instance, acknowledges that companies may provide certain support services which do not implicate the AKS. OIG Advisory Opinions further indicated—at the time of McKesson's alleged conduct here—that simply because a product or service has value does not necessarily mean that it violates the AKS. *See, e.g.*, OIG Adv. Op. No. 12-20 (concluding software products did not violate the AKS); OIG Adv. Op. No. 00-10 (concluding that providing information regarding insurance coverage and reimbursement did not violate the AKS).

Lastly, Hart relies on several cases in which there was no question that the defendant knew that direct payments to induce referrals violated the AKS—a situation plainly inapposite to the allegations here. *See, e.g.*, *United States v. Mittal*, 36 F. App'x 20 (2d Cir. 2006) (defendant received cash payments for referrals); *United States v. Nowlin*, 640 F. App'x 337 (5th Cir. 2016) (defendant agreed to refer clients in exchange for commissions); *United States v. Moshiri*, 858 F.3d 1077, 1082 (7th Cir. 2017) (defendant admitted that "his relationship with the Hospital had turned into receiving payment for patient referrals").

As before, while Hart's Complaint plausibly identifies conduct that could constitute unlawful inducement under the AKS, and that McKesson had general awareness of the AKS's

requirements, it fails to plausibly allege that McKesson provided the Margin Analyzer and Regimen Profiler to practices free of charge with the requisite scienter. *See, e.g.*, *Forney*, 2017 WL 2653568, at *4–*5 ("[Relator alleged] that the effect of the scheme was to induce physicians to refer Medtronic's products to their patients, [but had] not alleged that its subjective purpose was to do so."). Congress could have adopted a different scienter requirement when it passed the AKS, but specifically chose to impose the willfulness element that it did, and this Court is bound by that choice, as interpreted by the Second Circuit. *See Pfizer*, 42 F.4th at 77. Having failed to plausibly allege this scienter under the statute, Hart thus fails to state a claim as a matter of law, and McKesson's motion to dismiss is granted.

II. Leave to Amend

Whether to grant leave to further amend a complaint is committed to the "sound discretion of the district court." *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 200 (2d Cir. 2007). "Ordinarily, a plaintiff should be granted leave to amend at least once after having the benefit of a court's reasoning in dismissing the complaint." *Obra Pia Ltd. v. Seagrape Inv'rs LLC*, 2021 WL 1978545, at *3 (S.D.N.Y. May 18, 2021). This is especially true on the Court's first ruling on a motion to dismiss. *Loreley Financing (Jersey) No. 3 Ltd. v. Wells Fargo Secs. LLC*, 797 F.3d 160, 190 (2d Cir. 2015) ("Without the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies."); *see also Cresci v. Mohawk Valley Cmty. Coll.*, 693 F. App'x 21, 25 (2d Cir. 2017) ("The proper time for a plaintiff to move to amend the complaint is when the plaintiff learns from the District Court in what respect the complaint is deficient. Before learning from the court what are its deficiencies, the plaintiff cannot know whether he is capable of amending the complaint efficaciously."). "Granting leave to amend is futile," however, "if it appears that plaintiff cannot address the deficiencies identified by the court and allege facts sufficient to support the claim."

Panther Partners Inc. v. Ikanos Commc'ns, Inc., 347 F. App'x 617, 622 (2d Cir. 2009).

Here, Hart has already had the benefit of multiple rounds of amendment—the latest of which came after the Court granted leave to amend in a thirty-five-page opinion clearly delineating remaining deficiencies in the pleadings. *See* Prior Opinion, 602 F. Supp. 3d at 595 ("[T]o satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful . . . "). Even with the benefit of the Court's instruction, however, Hart has proven unable to plausibly allege that McKesson acted with the requisite scienter under the federal AKS.

Nevertheless, Hart's Complaint does bring claims under the FCA analogues of twenty-eight states, as well as the District of Columbia. Because "many of [those state law regimes] have their own analogous anti-kickback statutes," Compl. ¶ 13, it is conceivable that Hart could amend the pleadings to specifically allege that McKesson had the requisite scienter to violate the AKS counterparts of those states which do not incorporate the same "willfulness" standard, and thereby bring claims under those states' FCAs. To be sure, the Court is skeptical that it would retain jurisdiction over a possible Third Amended Complaint exclusively raising these state claims. *See, Kolari v. New York-Presbyterian Hosp.*, 455 F.3d 118, 122 (2d Cir. 2006) (the doctrine of pendent jurisdiction over state-law claims is traditionally "a doctrine of discretion, not of plaintiff's right"); *see also* 28 U.S.C. § 1367(c)(3) (clarifying a district court "may decline to exercise supplemental jurisdiction" if it has "dismissed all claims over which it has original jurisdiction"). But, in the exercise of its discretion, it nevertheless grants Hart leave for further amendment, should he have a good faith basis for doing so.

CONCLUSION

For the foregoing reasons, the motion to dismiss is granted without prejudice. The Clerk of Court is respectfully directed to terminate the motions pending at docket entries 171 and 174.[7]

SO ORDERED.

Dated: March 28, 2023
New York, New York

Hon. Ronnie Abrams
United States District Judge

[7] The Court grants in part and denies in part McKesson's motion to seal Exhibits 1(b)–1(d), 2, 4, and 5 to the Declaration of Nicholas Pastan, filed in conjunction with McKesson's motion to dismiss the Second Amended Complaint. *See* Dkt. 174.

While McKesson has established that portions of these documents relate to internal business and sales discussions, and that they include information from executive presentations and confidential business modeling, any sealing request must be narrowly tailored under *Lugosch v. Pyramic Co. of Onondaga*, 435 F.3d 110 (2d Cir. 2006), and related cases, to protect only "highly proprietary" commercial information from public disclosure, *GoSMiLE, Inc. v. Dr. Jonathan Levine, D.M.D. P.C.*, 769 F. Supp. 2d 630, 649–50 (S.D.N.Y. 2011) (allowing sealing of documents attached as exhibits where they "contain[ed] highly proprietary material concerning the defendants' marketing strategies, product development, costs and budgeting"). Accordingly, no later than April 28, 2023, McKesson is ordered to file proposed redacted versions of Exhibits 1(b)–1(d), 2, 4, and 5, specifically redacting only those portions of the documents that reflect such "highly proprietary" confidential business information.